REMARKS

This Amendment is responsive to the final Office Action dated February 10, 2009, and submitted with an RCE. Applicant has amended claims 18, 21 and 22, canceled claims 4–9, 11, 12, and 15–17, and added new claim 25. Claims 18–25 are pending.

In view of the above amendments and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections set forth in the final Office Action.

Claim Rejection Under 35 U.S.C. § 101

In the final Office Action, the Examiner rejected claims 17–21 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. In particular, the Examiner stated that claim 17 has no connection to a machine and produces no useful tangible result since a determination has not been made. By way of this Amendment, Applicant has canceled claim 17 and added new claim 25, from which claims 18–21 now depend. The method of Applicant's claim 25 is connected to a machine—a lead status monitor in an implantable medical device—and determines if a lead status event has occurred. For at least this reason, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 17–21 under 35 U.S.C. § 101.

Claim Rejections Under 35 U.S.C. § 112, First Paragraph

35 U.S.C. § 112, First Paragraph: Enablement

In the final Office Action, the Examiner rejected claims 17–24 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Initially, Applicant notes that the Examiner seems to be improperly applying the enablement requirement of 35 U.S.C. § 112, first paragraph. In particular, in explaining the enablement rejections, the Examiner repeatedly states that "the specification does not support" particular aspects of claims 17 and 22. However, this is not what is required to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. The pertinent part of 35 U.S.C. § 112, first paragraph states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same" (emphasis added). MPEP 2161.01(a) explains the enablement requirement as follows:

> A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Thus, the correct test of enablement is not whether the specification supports the claims, but whether the specification would have enabled one skilled in the art to make and use the claimed invention without undue experimentation. For at least this reason, the rejection of claims 17 – 24 under the enablement requirement of 35 U.S.C. § 112, first paragraph must be withdrawn.

Notwithstanding the Examiner's failure to apply the enablement requirement correctly, Applicant has canceled claim 17 and added new claim 25 to replace canceled claim 17, and has amended claim 22. Applicant will address the Examiner's enablement rejections under 35 U.S.C. § 112, first paragraph with respect to new claim 25 and amended claim 22.

The Examiner rejected claims 17–21 under 35 U.S.C. § 112, first paragraph because "the specification does not support using just one collected data but using all of them." Applicant respectfully disagrees with the Examiner's characterization of the teaching of Applicant's specification. Although Applicant's specification does indeed state that the LSM employs the weighted sum rules to process data from all the above-mentioned sources, Applicant's specification describes the various data sources in such a way that one of ordinary skill in the art would be able to make and use the claimed invention without undue experimentation. In addition, contrary to the Examiner's assertion, it would be clear to one of ordinary skill in the art that the specification supports using fewer than all the data sources, e.g., at least one of the data sources, in the weighted sum algorithm.

With respect to the enablement rejection, it seems intuitively obvious that a disclosure that enables one of ordinary skill in the art to perform a method on a plurality of data types enables one of ordinary skill in the art to perform the same method on a subset of the data types. For at least this reason, Applicant submits that the steps of collecting data relating to at least one of a percent of time in mode switch, an R-wave amplitude, a P-wave amplitude, a reversion pace count, a refractory sense count, a high rate episode count, and a time from implant, and processing the collected data, as recited by new claim 25, are enabled by Applicant's disclosure.

With respect to the specification supporting using only one collected data, Applicant's specification describes that, for example, that the refractory sense count may be included in the LSM weighted sum algorithm if the count increases. Implicitly, then, the refractory sense count may not be included in the LSM weighted sum algorithm if the count does not increase. Similarly, Applicant's specification describes that the high rate episode count may be included in the LSM algorithm. Implicit in this description is that the high rate episode count may not be included in the LSM algorithm. Based on at least these two descriptions, one of ordinary skill in the art would have understood that the various types of data may or may not be included in the LSM algorithm in different embodiments. Thus, Applicant's specification provides support for the steps recited in claim 25; namely, collecting data relating to at least one of a percent of time in mode switch, an R-wave amplitude, a P-wave amplitude, a reversion pace count, a refractory sense count, a high rate episode count, and a time from implant; and processing the collected data with an algorithm having a set of weighted sum rules.

The Examiner also rejected claims 17–21 under 35 U.S.C. § 112, first paragraph because "[t]he specification does not have support for using two distinct pathways to collecting (sic) data relating to one of a percent of time in mode switch, R-wave amplitude, P-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant." Applicant notes that new claim 25, from which claims 18–21 now depend, does not require use of two distinct pathways to collect recited types of data. For at least this reason, the this rejection of claims 17–21 is moot, and should be withdrawn.

The Examiner also rejected claims 17–21 under 35 U.S.C. § 112, first paragraph because "the specification does not provide support for running two different determination criteria on the separate pathways." Applicant notes that new claim 25, from which claims 18–21 now depend, does not require running two different determination criteria on the separate pathways. For at least this reason, this rejection of claims 17–21 is also moot, and should be withdrawn.

The Examiner rejected claims 22–24 under 35 U.S.C. § 112, first paragraph because the specification states "that the sensed events may be an indicator and that they are 'potential indicators', not that they identify the presence of a lead-related condition." Applicant respectfully disagrees. Applicant's specification states in numerous passages that the sensed events indicate or identify lead-related conditions. For example, page 4, line 32 to page 5, line 1 states, "[d]ata from these sources identifies lead conductor/connector issues, lead insulation

issues and electrode/tissue interface issues indicative of lead-related mechanisms suggestive of impending or actual lead failure for each lead employed in the IMD." Nevertheless, Applicant has amended claim 22 as suggested by the Examiner to advance prosecution of the application. Withdrawal of this rejection of claims 22–24 is requested.

Finally, the Examiner rejected claims 22–24 under 35 U.S.C. § 112, first paragraph because, "[a]lthough, the specification does state that it tests for events in both bipolar and unipolar mode it does not state if [it] creates a second event count." Applicant respectfully suggests that the specification clearly describes first and second event counts. For example, FIG. 8 and page 17, lines 15–29 describe, "During each counter window, the number of NPS events must exceed the nominal or programmed number, or trip point, which differs for unipolar sensing 136 and bipolar sensing 138. Each time the NPS event counts exceed the trip point in either 136 or 138, the number of 'successes' is registered in 140." In other words, a first count (e.g., an increment of 140) is generated when the number of NPS events exceeds the trip point for unipolar sensing 136, and a second count (e.g., an increment of 140) is generated when the number of NPS events exceeds the trip point for bipolar sensing 138. The LSM weighted sum algorithm then uses the number of trip points to determine whether a lead status condition may be present. For at least this reason, Applicant respectfully submits that the specification enables and describes creating a first count and a second count, and identifying the potential presence of a lead-related condition in response to the first event count and the second event count.

35 U.S.C. § 112, Second Paragraph: Indefiniteness

In the final Office Action, the Examiner rejected claims 17–21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has canceled claim 17 and added new claim 25, from which claims 18 – 21 now depend. Claim 25 positively recites a determining step, and has clarified the connection between the sensing signals and collected data. In addition, claim 25 no longer requires a first determination criterion. Applicant submits that the claims, as amended, particularly point out and distinctly claim the subject matter, as required by 35 U.S.C. § 112, second paragraph. Withdrawal of this rejection is respectfully requested.

Claim Rejections Under 35 U.S.C. §§ 102(b) and 103(a)

In the final Office Action, the Examiner rejected claims 17–19 under 35 U.S.C. § 102(b) as being anticipated by Schuelke et al. (U.S. Patent No. 5,755,742; hereafter "Schuelke"). In addition, the Examiner rejected claims 22 and 23 under 35 U.S.C. § 102(b) as being anticipated by Gillberg et al. (U.S. Patent No. 5,713,932; hereafter "Gillberg"). The Examiner also rejected claim 20 under 35 U.S.C. § 103(a) as being unpatentable over Schuelke as applied to claims 17–19 above, and further in view of Paul et al. (U.S. Patent No. 5,814,088; hereafter "Paul"). Applicant respectfully traverses the rejections to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no rational reason for modification to include such features, as required by 35 U.S.C. § 103(a).

Claims 17–21

As noted above, Applicant has canceled claim 17 and added new clam 25, from which claims 18 and 19 now depend. Applicant's claim 25 requires, in part, measuring an impedance along an electrical pathway and measuring a non-physiologic sensed event along the electrical pathway. Claim 25 also requires collecting data relating to at least one of a percent of time in mode switch, an R-wave amplitude, a P-wave amplitude, a reversion pace count, a refractory sense count, a high rate episode count, and a time from implant. In addition, claim 25 requires processing the collected data, the measured impedance and the non-physiologic sensed events with an algorithm having a set of weighted sum rules, wherein the algorithm assigns a value to each of the measured impedance, the measured non-physiologic sensed event, and each of the at least one of the percent of time in mode switch, the R-wave amplitude, the P-wave amplitude, the reversion pace count, the refractory sense count, the high rate episode count, and the time from implant.

In support of the rejection of previously presented claim 17, the Examiner characterized Shuelke as disclosing an implantable device that senses a p-wave amplitude and processes data to determine if there is a lead related event.[1]

While the Examiner was correct in stating that Schuelke discloses sensing a p-wave amplitude, Schuelke in no way discloses or suggests processing the p-wave amplitude to

[1] Final Office Action mailed February 10, 2009, page 6, line 22 to page 7, line 2.

determine if a lead status event has occurred. Schuelke discloses measuring the p-wave amplitude as part of monitoring a patient's heart rhythm for determining whether anti-bradycardia pacing, anti-tachycardia pacing, or anti-tachyarrhythmia shocks are needed to correct the patient's abnormal heart rate.[2] Schuelke does not disclose or suggest that the p-wave may be processed to determine if a lead status event has occurred. Schuelke also fails to disclose or suggest processing any other of the data recited in Applicant's claim 25, including a percent of time in mode switch, R-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant. In fact, Schuelke only discloses processing impedance of a conductive path to determine whether lead failure has occurred.[3]

In addition to processing at least one of a percent of time in mode switch, R-wave amplitude, P-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant, Applicant's claim 25 requires processing a measured impedance and a measured non-physiologic sensed event to determine if a lead status event has occurred. Schuelke fails to disclose or suggest measuring a non-physiologic sensed event, or processing a non-physiologic sensed event in combination with other data to determine if a lead status event has occurred. As described in Applicant's specification, non-physiologic sensed events are "transient, high frequency signals whose characteristics may be differentiated via sense amp filters from signal generated by intrinsic depolarization waveforms 120."[4] Schuelke fails to disclose or suggest measuring or processing non-physiologic sensed events.

In addition, Schuelke fails to disclose or suggest processing the collected data, the measured impedance and the non-physiologic sensed events with an algorithm having a set of weighted sum rules. The Examiner seems to recognize this by not rejecting over any prior art previously presented claim 21, which recited, in part, assigning weighted values to the collected data sets and summing the assigned weighted values to determine if one of a plurality of lead status events has occurred.

For at least these reasons, Schuelke fails to disclose or suggest the requirements of Applicant's claim 25. Paul fails to provide any disclosure sufficient to overcome the deficiencies of Schuelke. Claims 18–21 depend from claim 25 and are in condition for allowance for at least the reasons presented above. For at least these reasons, the Examiner has failed to establish a

[2] Schuelke, column 8, line 66 to column 9, line 7.
[3] *See, e.g., Id.* at column 14, lines 5–37.
[4] Applicant's originally filed Application, page 17, lines 3–5.

prima facie case for anticipation of Applicant's claims 25 and 18–21 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claims 22–24

Applicant has amended claim 22 to clarify that the claimed method includes determining whether a number of non-physiologic sensed events occurring along a first sensing pathway and determining a number of non-physiologic sensed events occurring along a second sensing pathway. As described above, non-physiologic sensed events are defined in Applicant's specification as "transient, high frequency signals whose characteristics may be differentiated via sense amp filters from signal generated by intrinsic depolarization waveforms 120."[5]

In support of the rejection of claim 22, the Examiner characterized Gillberg as disclosing "a method of determining lead dislocation that utilizes bipolar and unipolar electrodes to sense conduction times in each chamber of the atrium."[6] The Examiner further asserted that Gillberg discloses "determining intervals and incrementing a test counter for each chamber," and identifying a lead dislocation if the counter reaches a threshold value.[7]

As asserted by the Examiner, Gillberg measures conduction times and identifying a lead dislocation based on the conduction times. Gillberg fails to disclose or suggest the existence of non-physiologic sensed events as defined in Applicant's specification. Gillberg also fails to disclose or suggest determining whether a number of non-physiologic sensed events occurring along a first sensing pathway formed by one or more of the plurality of electrodes is greater than a first threshold associated with the first sensing pathway to generate a first event count and determining whether a number of non-physiologic sensed events occurring along a second sensing pathway formed by one or more of the plurality of electrodes, different from the first sensing pathway, is greater than a second threshold associated with the second sensing pathway to generate a second event count. Furthermore, Gillberg fails to disclose or suggest identifying the identifying the potential presence of a lead-related condition in response to the first event count and the second event count, as required by Applicant's claim 22.

Gillberg fails to disclose each and every limitation set forth in claim 22. Claims 23 and 24 depend from claim 22. For at least these reasons, the Examiner has failed to establish a prima

[5] Applicant's originally filed Application, page 17, lines 3–5.
[6] Final Office Action mailed February 10, 2009, page 7, lines 9–11.
[7] *Id.* at page 7, lines 11 and 12.

facie case for anticipation of Applicant's claims 22–24 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

New Claims:

Applicant has added claim 25 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claim 25, and provide no rational reason for modification to arrive at the claimed inventions, as described above. No new matter has been added by the new claim 25.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: May 11, 2009

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